

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

THE REGENTS OF THE UNIVERSITY OF
CALIFORNIA, ABBOTT MOLECULAR INC., and
ABBOTT LABORATORIES INC.,

No. C 05-03955 MHP

Plaintiffs,

v.

MEMORANDUM & ORDER
Re: Amendment of Basis for
Preliminary Injunction

DAKOCYTOMATION CALIFORNIA, INC.,

Defendant.

Plaintiffs The Regents of the University of California (“UC Regents”), Abbott Molecular Inc., and Abbott Laboratories Inc. (collectively, “Abbott”) brought this patent infringement action against defendant DakoCytomation California, Inc. (“Dako”), alleging infringement of two United States patents related to *in situ* DNA hybridization. On March 10, 2006 the court denied Abbott’s motion for a preliminary injunction. Abbott appealed the denial on March 30. The parties then appeared before the court for a status conference on April 17.

At the April 17 status conference, Abbott pointed out a potential defect in one section of the court’s order denying the preliminary injunction. Specifically, Abbott takes issue with the following passage:

The claims of the ‘479 patent have a further problem vis-à-vis the accused kit in that they are limited to the use of “a heterogeneous mixture of labeled unique sequence

nucleic acid fragments.” ‘479 patent at 16:9–10. Dako argues that this limitation excludes processes which employ probes corresponding to repetitive sequences. Plaintiffs argue that the phrase should be construed to mean “a heterogeneous mixture of labeled nucleic acid fragments that includes unique sequences,” but may also contain repetitive sequences.

Plaintiffs’ proposed construction is difficult to accept in light of the claims of the ‘841 patent, which is prior art to the ‘479 patent under 35 U.S.C. section 102(b). Claim 1 of the ‘479 patent explains that the “unique sequence nucleic acid fragments” are “substantially complementary to nucleic acid segments within the interphase chromosomal DNA *for which detection is desired*.” *Id.* at 16:10–13 (emphasis added). Likewise, the claims of the ‘841 patent require the use of “labeled nucleic acid that comprises fragments which are substantially complementary to nucleic acid segments within the chromosomal DNA *for which detection is desired*”—the very same phrase used in the ‘479 patent. ‘841 patent at 17:6–12 (emphasis added). Claim 1 of the ‘841 patent further requires “blocking nucleic acid that comprises fragments which are substantially complementary to repetitive segments in the labeled nucleic acid.” *Id.* Plaintiffs’ proposed construction suggests that the ‘479 patent, like the ‘841 patent, contemplates the use of both unique and repetitive probes. If this is true, plaintiffs’ proposed construction appears to eliminate much of the difference between the inventions claimed in the two patents.

Regeants of the Univ. of California v. DakoCytomation California, Inc., No. C 05-03955, 2006 WL 618769, at *9 (N.D. Cal. Mar. 10, 2006) (Patel, J.) (bold formatting added). According to Abbott, the bolded passage is an incorrect statement of the law because the ‘479 patent issued from a divisional of the same parent application that led to the ‘841 patent. Thus the claims of the ‘479 patent would be invalid in light of the ‘841 patent, if at all, under the court-created doctrines of obviousness-type (“nonstatutory”) double patenting. See generally Geneva Pharms., Inc. v. Glaxosmithkline PLC, 349 F.3d 1373 (Fed. Cir. 2003) (reviewing the origin of double patenting law). As Abbott notes, certain patents issued from divisional applications receive special protection from double patenting challenges under 35 U.S.C. section 121. When the PTO imposes restriction requirements limiting the scope of the invention claimed on an application, the resulting applications and patents “shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them.” 35 U.S.C. § 121.

Although sections 102 and 103 do not provide the proper framework for analyzing the differences between the claims of the ‘479 and ‘841 patents, double patenting law requires that divisional applications claim “independent and distinct inventions,” a standard which is similar to the standards for anticipation or obviousness. Geneva Pharms., 349 F.3d at 1377–78. Indeed, the

1 standard for nonstatutory double patenting is stricter in some ways than the standard for obviousness
2 under section 103: “Obviousness requires inquiry into a motivation to modify the prior art;
3 nonstatutory double patenting does not; . . . Obviousness requires inquiry into objective criteria
4 suggesting non-obviousness; nonstatutory double patenting does not.” Id. at 1377 n.1. Moreover,
5 the protection afforded under section 121 is limited and strictly construed:


6 [T]his court applies a strict test for application of § 121. Specifically, § 121 only
7 applies to a restriction requirement that is documented by the PTO in enough clarity
8 and detail to show consonance. The restriction documentation must identify the
scope of the distinct inventions that the PTO has restricted, and must do so with
sufficient clarity to show that a particular claim falls within the scope of the distinct
inventions.

9 Id. at 1382. The burden is on the patent holder to prove that section 121 applies. Id.

10 The court therefore amends its previous order to the extent that it improperly cites 35 U.S.C.
11 section 102 as the basis for questioning the validity of the claims of the ‘479 patent in light of the
12 earlier-issued claims of the ‘841 patent. Instead, the court questions the validity of the later-issued
13 claims based on the doctrine of nonstatutory double patenting.

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18 IT IS SO ORDERED.

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21 Date: May 17, 2006

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MARILYN HALL PATEL
United States District Judge
Northern District of California